

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated November 16, 2004 are respectfully requested. Applicants petition the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

I. Rejection under 35 U.S.C. § 102

Claims 38-42 and 45-71 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,683,384).

Claims 38-42 and 45-71 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,800,484).

These rejections are respectfully traversed.

A. The Present Invention

The present invention relates to an ablation apparatus comprising (i) an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue, and (ii) an impedance array. The impedance array comprises a plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state. The resilient members define a sample volume in the deployed state. At least two of the plurality of resilient members are a sensor member and includes a sensor for determining impedance, where each sensor member is operatively connected to a separate impedance energy source. At least some of said resilient members are electrodes which can be coupled to at least one ablating energy source for ablating tissue when electrical energy is supplied to the electrodes from the source. The impedance array is effective to determine localized impedance.

B. The Prior Art

GOUGH ET AL. (THE '384 PATENT) relate to a multiple arm device including a primary arm with a longitudinal axis, and a secondary arm coupled to the primary arm. The

secondary arm is configured to be deployed in a direction that is lateral to the longitudinal axis with at least one radius of curvature. The device may further include a multiplexer coupled to the primary antenna, the secondary antenna, and the energy source to multiplex between the primary and secondary antennas.

GOUGH ET AL. (THE '484 PATENT) describe an ablation apparatus comprising an introducer, two or more electrodes at least partially positioned in the introducer lumen, wherein each electrode is configured to be advanced from the introducer to define a volumetric ablation volume, and a porous fluid delivery member positioned on at least a portion of an exterior of at least one of the electrodes.

C. Analysis

According to M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

C1. Rejection of the '384 patent

The '384 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the present invention. The Examiner "maintains that the Gough et al. disclosure inherently suggests the use of different energy sources for each electrode/sensor member" (page 3, Final Office action mailed November 16, 2004).

The legal standard with respect to inherent anticipation is that "inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may result* from a given set of circumstances is insufficient to prove anticipation."

Contentental Can Co. v. Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981).

Applying this legal standard to the present facts, the claimed feature that each sensor member is operatively connected to a separate impedance energy source must necessarily be present in the disclosure of the '384 patent. Such a disclosure is not

necessarily present in the '384 patent. The '384 patent teaches a variety of energy sources, "[e]nergy source 20 can be an RF source, microwave source, short wave source, laser source and the like...Energy source 20 may be a combination RF/microwave box" (Col. 6, lines 35-42), as noted by the Examiner. While the Examiner maintains that this recitation teaches "that a plurality of energy sources may be connected to individual electrodes/sensors" (page 5, Final Office action mailed November 16, 2004), Applicants disagree. There is nothing in this recitation of energy sources that teaches or even suggests that a separate energy source is connected to each individual electrode. Rather, the recitation is a mere listing of suitable energy sources. Even if the recitation were to be construed as a teaching of multiple energy sources, there are many possible configurations other than each sensor member being connected to a separate energy source. For example, the recitation of various energy sources could also be construed as either of (i) some of the electrodes being connected to a first energy source and some electrodes being connected to a second energy source, or (ii) all of the electrodes being connected to a combination microwave/RF box. Thus, it does not necessarily follow from this recitation in the '384 patent of a variety of energy sources that each sensor member be operatively connected to a separate impedance energy source.

Although the '384 patent may include electrodes that may be switched between energy sources (i.e. RF and microwave sources), this is certainly not even suggestive of a separate energy source for each sensor member as all of the electrodes may be connected to both sources, may be connected to one source, albeit a combination source (Col. 6, lines 41-42), or all of the electrodes may also be connected to a multiplexer that switches between energy sources.

As there are many possible configurations that could result from the '384 patent teaching of a variety of energy sources, it cannot necessarily follow that each electrode is connected to a separate energy source based on this disclosure. Thus, withdrawal of the rejection based on the '384 patent is respectfully requested.

C2. Rejection of the '484 patent

The '484 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the present invention. The '484 patent makes no mention of a separate energy source for any of the deployable elements.

The disclosure of the '484 patent does not inherently anticipate the claimed method, for all the reasons given above in section C1.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

II. Rejections under 35 U.S.C. §103

Claims 38-42 and 45-71 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.*, the '384 patent.

Claims 38-42 and 45-71 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.*, the '484 patent.

These rejections are respectfully traversed.

A. The Present Invention

The present invention is described above.

B. The Prior Art

GOUGH ET AL., THE '384 PATENT is described above.

GOUGH ET AL., THE '484 PATENT is described above.

C. Analysis

According to MPEP § 2143, "to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

The Examiner states "the use of a separate source for each electrode/sensor member would be an obvious consideration in view of the Gough et al. teaching of using a combination of sources for the electrode/sensor members" (pages 3 and 4, Final Office action mailed November 16, 2004).

As noted above, neither of the '384 nor the '484 patents expressly or inherently disclose at least two sensor members that include a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source. Nor would it be obvious to connect each sensor member to a separate energy source. The present invention is particularly concerned with using localized impedance measurement to detect, locate and identify tumorous tissue as well as monitor a target tissue site and control the course of ablative therapy. In another embodiment, the localized impedance measurements may be used to generate an image of a target tissue site and display the image to facilitate the location and monitoring of a tumor and/or ablation volume.

Attempts to measure impedance using a full electrical circuit through the patient's body have the drawback of not being able to detect tissue localized impedance. Problems include (i) the signal is too small in relation to and/or masked out by the impedance of the entire impedance measurement system; (ii) the measurement was made too far away on the body from the desired tissue site and is thus masked out; and (iii) the localized impedance was masked out by RF or other ablative energy signal delivered to the tissue. These problems are solved in the present apparatus by having at least two sensor members that include a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source.

Neither the '384 nor the '484 patents are particularly concerned with detecting localized impedance nor the problems associated with detecting localized impedance. As neither of the '384 nor the '484 patents expressly teach the claimed feature nor are

particularly concerned with the problem, the presently claimed feature cannot be said to be an "obvious variation" of the teaching in the '384 and '484 patents.

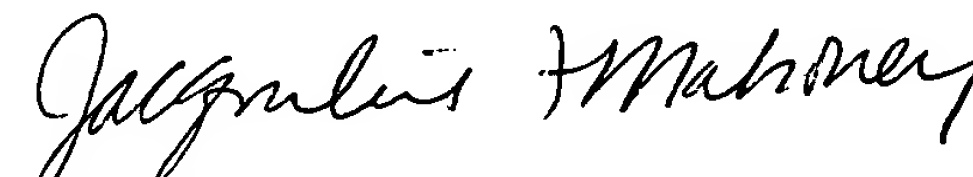
In view of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,



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